DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JUL 27 2015

Olympus Medical Systems Corp.
% Ms. Stacy Abbatiello Kluesner, M.S., RAC
Regulatory Affairs Project Manager
Olympus America, Inc.
3500 Corporate Parkway
Center Valley, PA 18034-0610

Re: K100345
Trade/Device Name: SYSTEMS INTEGRATION ENDOALPHA
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODA, GCJ
Dated (Date on orig SE ltr): February 5, 2010
Received (Date on orig SE ltr): February 24, 2010

Dear Ms. Kluesner,

This letter corrects our substantially equivalent letter of March 22, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100345

Device Name: SYSTEMS INTEGRATION ENDOALPHA

Indications for Use:

The Systems Integration ENDOALPHA has been designed to be used with an Olympus endoscope and ancillary equipment for central operation, central display, automatic initial setting, and interlocking operation of the ancillary equipment.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K100345

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510(k) SUMMARY

MAR 22 2010

SYSTEMS INTEGRATION ENDOALPHA

January 29, 2010

1 General Information

■ Applicant:

OLYMPUS MEDICAL SYSTEMS CORP.
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Manufacturer:

SHIRAKAWA OLYMPUS CO., LTD.
3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
Nishishirakawa-gun
Fukushima, JAPAN 961-8061
Establishment Registration No: 3002808148

2 Device Identification

■ Device Name:	SYSTEMS INTEGRATION ENDOALPHA
■ Common Name:	Endosurgery system
■ Regulation No:	21 CFR 876.1500
■ Regulation Name:	Endoscope and accessories
■ Regulatory Class:	II
■ Product Code:	KOG, GCJ
■ Classification Panel:	Gastroenterology/Urology
■ Prescription Status:	Prescription device
Performance Standards:	None established under Section 514.

: 00336

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3 Predicate Device Information

■ Device Name:	Olympus Integrated Endosurgery System EndoALPHA (Control Unit for Endosurgery UCES-2) Software Version 3
■ 510(k) No:	K051613
■ Decision Date:	08/15/2005

4 Device Description

The Systems Integration ENDOALPHA has been designed to be used with an Olympus endoscope and ancillary equipment for central operation, central display, automatic initial setting, and interlocking operation of the ancillary equipment.

The ENDOALPHA integrated electrosurgical system has the following system functions.

1) Centralized control from a non-sterilized area
The ancillary equipment connected to the MEDICAL CONTROL UNIT FOR ENDOSURGERY (UCES-3) and EXTENSION UNIT FOR UCES-3 (MAJ-1827) can be controlled in a centralized way using the TOUCH PANEL FOR ENDOALPHA (MAJ-1828).

2) Centralized control from a sterilized area
- Ancillary equipment can be controlled by means of voice from a sterilized area.
- Ancillary equipment can be controlled utilizing remote switches of the endoscope connected to the VIDEOSYSTEM CENTER (OLYMPUS CV-180, OLYMPUS OTV-S7Pro) in a sterilized area.

3) Centralized display
The settings of the functions of connected ancillary equipment can be displayed on the screen of the TOUCH PANEL FOR ENDOALPHA (MAJ-1828) and UNIVERSAL DISPLAY FOR ENDOALPHA (MAJ-1176).

4) Message display
Various warning and error messages can be displayed on the screen of the TOUCH PANEL FOR ENDOALPHA (MAJ-1828) and UNIVERSAL DISPLAY FOR ENDOALPHA (MAJ-1176).

5) Voice reply
The ancillary equipment settings, warning messages, error messages can be fed back in voice.

6) Automatic settings
The default settings of all ancillary equipment can be registered on a per-procedure basis and recalled with a one-touch operation for setting the ancillary equipment to the required settings at once.

7) Scene settings
The operations of the ancillary equipment, performed at the beginning of each scene in the procedure, can be registered and recalled with a one-touch operation for performing them at once.

8) Display customization
The contents of the display of the TOUCH PANEL FOR ENDOALPHA (MAJ-1828) and UNIVERSAL

DISPLAY FOR ENDOALPHA (MAJ-1176) can be customized.

9) Still image viewing
Still images recorded in a USB thumb drive (SDCZ8) can be viewed on the UNIVERSAL DISPLAY FOR ENDOALPHA (MAJ-1176).

10) Automatic smoke evacuation
When a recommended electrosurgical unit and/or SonoSurg Generator (SonoSurg-G2) and an insufflator are connected to the MEDICAL CONTROL UNIT FOR ENDOSURGERY (UCES-3) or EXTENSION UNIT FOR UCES-3 (MAJ-1827), the generated smoke or vapor can be evacuated automatically.

The modifications made to the subject device are as follows:
A) Addition or deletion of recommended ancillary equipment
B) A change involving the communication interface
C) A change in the design of the Graphical User Interface (GUI)
D) Addition of a voice reply function
E) Deletion of Surgeon's controller for EndoALPHA (MAJ-1140)
F) Transfer of Input/Output function for video signals to the Advanced system
G) Addition of additional connectable touch panel
H) Addition of Scene settings function
I) Addition of system components
J) Changes to the specifications of system components

5 Intended Use

The Systems Integration ENDOALPHA has been designed to be used with an Olympus endoscope and ancillary equipment for central operation, central display, automatic initial setting, and interlocking operation of the ancillary equipment.

The intended use of the ENDOALPHA as stated above is to enable a central system to control various pieces of ancillary equipment. However, the previously cleared indications for use for each separate ancillary device dictate the type of procedures that may be performed. This information is included in the instruction manual for each ancillary piece of equipment.

The Intended Use is identical to the Intended Use previously cleared for the Olympus Integrated Endosurgery System EndoALPHA (Control Unit for Endosurgery UCES-2) Software Version 3, K051613.

6 Conclusion

The modified SYSTEMS INTEGRATION ENDOALPHA has the following similarities to the predicate device:
- Has the same intended use,
- Uses the same operating principle

In summary, the modified SYSTEMS INTEGRATION ENDOALPHA described in this submission is, in our opinion, substantially equivalent to the predicate device.